

STOOL SOFTENER- docusate sodium tablet
STRATEGIC SOURCING SERVICES LLC

sun 421

Active ingredient

Docusate Sodium 100 mg

Purpose

Stool Softener Laxative

Uses

- relieves occasional constipation (irregularity)
- generally produces bowel movement in 12 to 72 hours

Warnings

Ask a doctor before use if you

- have stomach pain, nausea or vomiting
- have a sudden change in bowel habits that persists over a period of 2 weeks
- are presently taking mineral oil

Stop use and ask a doctor if

- you need to use a laxative longer than 1 week
- you have rectal bleeding or fail to have a bowel movement. These could be signs of a serious condition.

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children

Keep out of the reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- adults and children 12 years and older: take 1-2 tablets daily until first bowel movement; 1 tablet daily thereafter, or as directed by doctor
- children under 12: consult a doctor
- do not exceed recommended dose

Other information

- **each tablet contains:** calcium 50 mg, sodium 8 mg
- for institutional use only
- package not child resistant
- store at room temperature 15°C-30°C (59°F-86°F)
- **Tamper Evident:** Do not use if imprinted seal under cap is missing or broken

Inactive ingredients

cellulose, croscarmellose sodium, dicalcium phosphate, magnesium stearate, silica, stearic acid, talc

PACKAGE LABEL



stool softener

For relief of occasional constipation
DOCUSATE SODIUM 100 mg

100 TABLETS

ACTUAL SIZE

COMPARE TO COLACE®
ACTIVE INGREDIENT*
NDC 49348-167-10



stool softener

DOCUSATE SODIUM
100 mg

100 TABLETS



stool softener

For relief of occasional constipation
DOCUSATE SODIUM 100 mg

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ACTUAL SIZE

COMPARE TO COLACE®
ACTIVE INGREDIENT*
NDC 49348-167-10

TAMPER EVIDENT: DO NOT USE IF IMPRINTED SEAL UNDER CAP IS MISSING OR BROKEN.

SAVE CARTON FOR COMPLETE DRUG FACTS	
Drug Facts	Purpose
Active ingredient (in each tablet) Docusate Sodium 100 mg	Stool Softener Laxative
Uses	
<ul style="list-style-type: none"> relieves occasional constipation (irregularity) this product generally produces a bowel movement in 12 to 72 hours 	
Warnings	
<p>Ask a doctor before use if you • have stomach pain, nausea or vomiting • have a sudden change in bowel habits that persists over a period of 2 weeks • are presently taking mineral oil</p> <p>Stop use and ask a doctor if • you need to use a laxative longer than 1 week • you have rectal bleeding or fail to have a bowel movement. These could be signs of a serious condition.</p> <p>If pregnant or breast-feeding, ask a health professional before use.</p> <p>Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.</p>	
Drug Facts (continued)	
Directions	
<ul style="list-style-type: none"> adults and children 12 years and older: take 1-2 tablets daily until first bowel movement; 1 tablet daily thereafter, or as directed by doctor children under 12: consult a doctor do not exceed recommended dose 	
Other information	
<ul style="list-style-type: none"> each tablet contains: calcium 50 mg, sodium 8 mg store at room temperature 15°-30°C (59°-86°F) 	
Inactive ingredients: cellulose, croscarmellose sodium, dicalcium phosphate, magnesium stearate, silica, stearic acid, talc.	
Questions or Comments? 1-800-540-3765	



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REV GC421-1217

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STOOL SOFTENER

docusate sodium tablet

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:49348-167

Route of Administration		ORAL		
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
DOCUSATE SODIUM (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG)		DOCUSATE SODIUM	100 mg	
Inactive Ingredients				
Ingredient Name			Strength	
STEARIC ACID (UNII: 4ELV7Z65AP)				
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)				
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)				
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
TALC (UNII: 7SEV7J4R1U)				
Product Characteristics				
Color	white	Score	no score	
Shape	ROUND	Size	11mm	
Flavor		Imprint Code	GC422	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49348-167-10	1 in 1 CARTON	03/01/2016	
1		100 in 1 BOTTLE; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M007	03/01/2016		

Labeler - STRATEGIC SOURCING SERVICES LLC (116956644)

Registrant - GCP Laboratories (965480861)

Establishment			
Name	Address	ID/FEI	Business Operations
GCP Laboratories		965480861	manufacture(49348-167)

